

REMARKS

Claims 15-48 have previously been withdrawn from consideration as being drawn to non-elected subject matter. In the interest of moving the application towards allowance, claims 15-48 are hereby cancelled. Claim 49 has also been cancelled. Claims 50-57 have been amended to change the dependency, and new claim 58 has been added. Accordingly, claims 50-58 are pending in this application. Reconsideration is respectfully requested.

Applicants note that the advisory action indicates that claims 49-57 are pending in the application. As stated above, claims 50-58 are presently pending in the application.

New claim 58 has been added which more clearly defines the invention. As claim 58 recites, the glycoprotein matrix is derived from yeast and bacteria. Support for new claim 58 can be found on page 9, lines 24-25 of the application.

REJECTION UNDER 35 U.S.C. §112

Claims 49-57 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Specifically, the Examiner has pointed out that the recitation of "the ubiquinone" in claim 49 (erroneously referred to as claim 1) lacks antecedent basis. In response, Applicants have cancelled claim 49 and added claim 58 which recites "the coenzyme Q10" for which there is antecedent basis.

Accordingly, Applicants respectfully request the rejection based on §112 be withdrawn.

REJECTIONS UNDER 35 U.S.C. §102

Claims 49 and 57 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,804,555 to Tomita et al. According to the Examiner, Tomita et al. teach antioxidant compositions comprising lactoferrin hydrosylates and coenzyme Q, and therefore, the Examiner contends that the claimed invention is anticipated. Applicant respectfully disagrees.

The present invention is a composition comprising a glycoprotein matrix bound to coenzyme Q10 ("CoQ10"), wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals.

Lactoferrin is a glycoprotein that is found in mammalian milk. See column 2, lines 22-33 of Tomita et al. Lactoferrin is not produced by yeast or bacteria.

Nowhere in Tomita et al. is there any disclosure of a glycoproteins derived from yeast and bacteria bound to CoQ10, nor is there any suggestion that lactoferrins are bound to CoQ10. Tomita et al. merely disclose admixtures containing lactoferrin and various antioxidants.

In sum, because Tomita et al. do not disclose a composition comprising a glycoprotein matrix bound to CoQ10, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals, Tomita et al. does not anticipate the claimed invention.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on Tomita et al. be reconsidered and withdrawn.

Claims 49-51, 54 and 57 have been rejected under 35 U.S.C. §102(b) as being anticipated by GB 2178622 A to Seuref. The Examiner alleges that Seuref teaches compositions of CoQ10 and brewer's yeast.

As mentioned above, the present invention is for a composition comprising a glycoprotein matrix bound to CoQ10, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals.

Seuref provides a dry yeast extract and coenzyme Q admixture. Seuref does not teach a composition comprising a glycoprotein matrix bound to CoQ10 wherein the glycoprotein matrix is derived from yeast and bacteria.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on Seuref be reconsidered and withdrawn.

Claims 49, 54 and 57 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,658,648 to Nakao et al. The Examiner contends that Nakao et al. teach compositions of coenzyme Q10 wherein yeasts are fermented to produce coenzyme Q10. The Examiner further states that Nakao teaches that ubiquinones are obtainable by incubating bacteria and *S. cerevisiae*. Therefore, the Examiner states that Nakao et al. anticipate the claimed invention.

Applicant respectfully disagrees. Nakao does not teach how to produce a composition comprising CoQ10 at all. In col. 1, lines 25-48 of Nakao (which the Examiner relies upon), Nakao disclose that it is known that coenzyme Q is contained in the cells of various kinds of microorganisms. Specifically, Nakao states that it is known that CoQ10 is contained in the cells of *Pseudomonas denitrificans* and *Neurospora crassa*. See col. 1, lines 42-43.

Neither *Pseudomonas denitificans* or *Neurospora crassa* are suitable for consumption by mammals. There is no disclosure or suggestion in Nakao of a composition comprising a glycoprotein matrix bound to CoQ10, wherein the glycoprotein matrix is derived from bacteria and yeast.

Nakao is simply disclosing a method for producing a specific species of coenzyme Q. Nakao discloses only methods for obtaining CoQ8 and CoQ9 by incubating specific strains of bacteria or yeast, not both. See Examples 1-7 of Nakao.

In contrast, the present invention is concerned with CoQ10 bound to a glycoprotein matrix that is derived from yeast and bacteria. Because the glycoprotein matrix is bound to the CoQ10, the claimed composition possesses improved properties when compared to conventional CoQ10 compositions (e.g. admixtures). For example, the claimed composition has increased stability when compared to conventional CoQ10 compositions. See Example 3 and Table 2 of the application.

Importantly, the claimed composition has increased bioactivity. For instance, in Example 2 and Table 1 of the application, coenzyme Q10 bound by a glycoprotein matrix demonstrates antioxidant activity that is 20 times greater than commercially available (e.g. unbound) coenzyme Q10.

There is simply no teaching in Nakao of a composition comprising a glycoprotein matrix bound to CoQ10, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on Nakao et al. be reconsidered and withdrawn.

Claims 49, 52-53 and 55-57 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,895,652 to Giampapa. The Examiner alleges that Giampapa teaches a nutritional supplement comprising hesperidin, coenzyme Q10 and lipase, and therefore, the Examiner contends that the claimed invention is anticipated by Giampapa. Applicant respectfully disagrees.

The present invention is a composition comprising a glycoprotein matrix bound to CoQ10, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals.

Importantly, Giampapa does not disclose a glycoprotein matrix derived from yeast and bacteria, as in the claimed invention. Giampapa discloses a composition containing fifty or so various ingredients, including lipase (which the Examiner characterizes as a glycoprotein).

Lipase is an enzyme secreted by the pancreas to aid in the digestion of fat. Lipase is not derived from yeast and bacteria. Giampapa does not disclose a composition comprising a glycoprotein matrix bound to CoQ10, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals. Therefore, Giampapa does not anticipate the claimed invention.

Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) based on Giampapa be reconsidered and withdrawn.

REJECTIONS UNDER 35 U.S.C. §103

Claims 1-4 and 14 have been rejected under 35 U.S.C §103(a) as being unpatentable over Nakao. According to the Examiner, Nakao teaches compositions of CoQ10 wherein yeasts are fermented to produce CoQ10, and that ubiquinones are obtainable from bacteria and *S. cerevisiae*.

The Examiner recognizes that Nakao does not teach the compositions with the claimed amounts or ratios of Q10 to glycoprotein. However, the Examiner contends that it would have been obvious at the time of the invention to optimize such volumes and ratios as a matter of routine experimentation. Applicants respectfully disagrees.

Nakao et al. do not teach the amounts of ubiquinone or the ratio of ubiquinone to glycoprotein as in the claimed invention because Nakao et al. are not adding ubiquinone to a composition. Rather, as discussed above, Nakao et al. disclose a process for encouraging the production of coenzyme Q.

As discussed above, there is no disclosure or suggestion in Nakao of a composition comprising a glycoprotein matrix bound to CoQ10 wherein the glycoprotein matrix is derived from bacteria and yeast.

The claimed invention requires that the glycoprotein matrix be derived from yeast and bacteria.

In order to establish a *prima facie* case of obviousness, one criteria to be met is that the prior art reference must teach or suggest all of the claim limitations. See MPEP §2142.

Applicant has demonstrated the importance of the CoQ10 being bound to a glycoprotein matrix, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals..

Nakao does not teach or suggest all of the claimed limitations of the present invention. Therefore, based on the foregoing discussion, Applicant's claimed invention is not obvious over Nakao. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §103(a) based on Nakao be reconsidered and withdrawn.

Claims 49-53 and 57 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa. The Examiner recognizes that Giampapa fails to disclose the volume or ratio of coenzyme Q10 to glycoprotein as in the claimed invention. However, the Examiner alleges that it would have been obvious to one of ordinary skill to optimize such ratios.

As discussed above, Giampapa teaches a nutritional supplement comprising hesperidin, coenzyme Q10, lipase and algae. Giampapa does not disclose or suggest a composition comprising a glycoprotein matrix bound to CoQ10, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals.

In order to establish a *prima facie* case of obviousness, one criteria to be met is that the prior art reference must teach or suggest all of the claim limitations. See MPEP §2142.

Applicant has demonstrated the importance of the CoQ10 being bound to a glycoprotein matrix, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals..

Giampapa do not teach or suggest all of the claimed limitations of the present invention. Therefore, based on the foregoing discussion, Applicant's claimed invention is not obvious over Giampapa. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §103(a) based on Giampapa be withdrawn.

Claims 49-51 (erroneously referred to as 49-41) and 55-57 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Metz and Kruzel. The Examiner contends that Metz teaches a food supplement for aiding the intestines comprising CoQ10 and *Lactobacillus acidophilus*, and Kruzel teaches a food supplement for preventing microbial infections comprising lactoferrin.

The Examiner recognizes that Metz and Kruzel do not teach the ingredients in a single composition. However, the Examiner alleges that it would have been obvious to one of ordinary skill to combine the instant ingredients for their known benefit.

As stated above, the claimed invention is for a composition comprising a glycoprotein matrix bound to CoQ10, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals.

Lactoferrin is not a glycoprotein derived from yeast and bacteria. Neither Metz or Kruzel disclose glycoproteins derived from yeast and bacteria.

In order to establish a *prima facie* case of obviousness, one criteria to be met is that the prior art references, when combined, must teach or suggest all of the claim limitations. See MPEP §2142.

Applicant has demonstrated the importance of the CoQ10 being bound to a glycoprotein matrix, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals.

Upon combining the teachings of Metz or Kruzel, all of the claimed limitations of the present invention are not disclosed or suggested. Therefore, based on the foregoing discussion, Applicant's claimed invention is not obvious over Metz and Kruzel. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. §103(a) based on Kurzinger be reconsidered and withdrawn.

Response to Comments in Advisory Action

In the advisory action, the Examiner contends that the previously filed amendment did not place the application in condition for allowance because new claim 58 allegedly raises new issues that would require further consideration or a new search. In addition, the Examiner notes that patentability of a composition does not depend on the process of making the composition if it does not materially change the final product. The Examiner goes on to state that Nakao teaches fermentation of a yeast and/or bacteria in the presence of CoQ10. Applicant respectfully disagrees.

As mentioned above, the pending claims are directed to a composition comprising a glycoprotein matrix bound to coenzyme Q10, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals, and is bound to the coenzyme Q10 by fermenting the yeast and bacteria in the presence of coenzyme Q10.

In the Examples presented in the application, it is shown that a CoQ10 composition according to the claims is superior to other CoQ10 compositions (e.g. twenty times greater antioxidant activity, increased stability). The superiority of the claimed CoQ10 composition is due to the claimed fermentation process using both yeast and bacteria.

Applicants have discovered that fermenting yeast and bacteria in the presence of CoQ10 produces CoQ10 bound by the glycoprotein matrix that is secreted by the yeast and bacteria.

As mentioned above, Nakao discloses only a method for producing coenzyme 8 and coenzyme 9 by incubating either a yeast or a bacterium to encourage the microorganism to secrete the coenzyme 8 or 9. Furthermore, Nakao teaches using a culture medium containing mainly hydrocarbons which encourages the microorganism to produce large amounts of the coenzyme, not glycoproteins.

In stark contrast, the present invention aims to encourage the microorganisms to produce glycoproteins by using a medium containing carbohydrates, such as maltose. See page 10, lines 25-30 and page 11, lines 1-12 of the application.

In sum, the final product of the present invention is quite distinct from that of Nakao. Therefore, Applicants respectfully requests that the Examiner reconsider the above rejections.

In light of the foregoing amendments and remarks, Applicant respectfully submits that the application is now in condition for allowance. If the Examiner believes a telephone discussion with the Applicant's representative would be of assistance, she is invited to contact the undersigned at her convenience.

Respectfully submitted,



Lauren T. Emr
Attorney for Applicant
Reg. No. 46,139

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(516) 822-3550
LTE/nr

This listing of claims will replace all prior versions, and listings, of claims in the application:

Please cancel claims 15-49;

Please add new claim 58 as follows:

Please amend claims 50-57 as follows:

Claims 1-49 (Canceled)

50. (Currently Amended) A composition as described in Claim 49 58, wherein said coenzyme Q10 is present in an amount between about 5% and 15% by weight of said composition.

51. (Currently Amended) A composition as described in Claim 49 58, wherein the ratio of said glycoprotein matrix to said coenzyme Q10 is between about 1:1 to about 10:1.

52. (Currently Amended) A composition as described in Claim 49 58, further comprising a bioflavonoid.

53. (Currently Amended) A composition as described in Claim 49 52, wherein said bioflavonoid is hesperidin.

54. (Currently Amended) A composition as described in Claim 49 58, wherein said yeast include *Saccharomyces cerevisiae*.

55. (Currently Amended) A composition as described in Claim 49 58, wherein said bacteria comprises bacteria within genus *Lactobacillus*.

56. (Currently Amended) A composition as described in Claim 49 58, wherein said bacteria includes *Lactobacillus acidophilus* or *Bacterium bifidus*, or both.

57. (Currently Amended) A nutritional supplement comprising coenzyme Q10 bound by a glycoprotein matrix according to claim 49 58.

58. (New) A composition comprising a glycoprotein matrix bound to coenzyme Q10, wherein the glycoprotein matrix is derived from yeast and bacteria suitable for consumption by mammals, and is bound to the coenzyme Q10 by fermenting the yeast and bacteria in the presence of coenzyme Q10.